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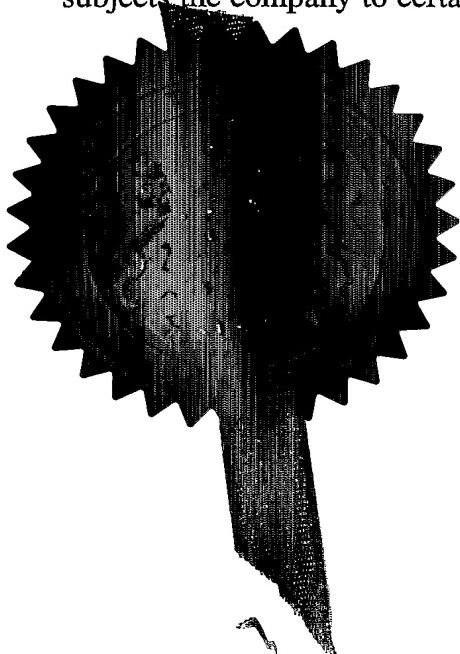
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an explanatory leaflet from the Patent Office to help you fill in this form)

31 AUG 2004

1. Your reference 1060/853/P/GB

2. Patent application number
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0419260.5

3. Full name, address and postcode of the or of each applicant (underline all surnames)
Boots Healthcare International Limited
1 Thane Road West
Nottingham
NG2 3AA

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

England

08504136001

4. Title of the invention Skincare Compositions and Methods

5. Name of your agent (if you have one) Adamson Jones

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)
Broadway Business Centre
32a Stoney Street
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Patents ADP number (if you know it)

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Country	Priority application number (if you know it)	Date of filing (day / month / year)
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7. Divisionals, etc: Complete this section only if this application is a divisional application or resulted from an entitlement dispute (see note 6)

Number of earlier application	Date of filing (day / month / year)
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8. Is a Patents Form 7/77 (Statement of inventorship and of right to grant of a patent) required in support of this request? (Answer 'yes' if:
 a) any applicant named in part 3 is not an inventor, or
 b) there is an inventor who is not named as an applicant, or
 c) any named applicant is a corporate body.
 See note (d))

Yes

Patents Form 1/77

9. Accompanying documents: A patent application must include a description of the invention. Not counting duplicates, please enter the number of pages of each item accompanying this form:

Continuation sheets of this form

Description	21
Claim(s)	5
Abstract	0
Drawing(s)	0

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translation of priority documents

Statement of inventorship and right to grant of a patent (*Patents Form 7/77*)

Request for a preliminary examination and search (*Patents Form 9/77*)

Request for substantive examination
(*Patents Form 10/77*)

Any other documents
(please specify)

11.

I/We request the grant of a patent on the basis of this application.

Signature

Date
31 August 2004

12. Name, daytime telephone number and email address, if any, of person to contact in the United Kingdom

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Title – Skincare Compositions and Methods

This invention relates to skincare compositions, in particular compositions
5 effective in the treatment of acne vulgaris, and to methods of treatment of the
skin that involve the application of such compositions.

Acne vulgaris (acne) is a chronic inflammatory condition of the
pilosebaceous units of the skin, which is particularly prevalent in
10 adolescents. The condition generally causes the formation, on the skin, of
comedones, red papules, pustules and sometimes cysts. This is unsightly
and furthermore, if untreated, acne can lead to scarring of the skin. The
major causes of acne are thought to be an increase in sebum production, an
increased presence of *propionibacterium acne* (*P. acne*), blockage of the
15 pilosebaceus duct and the production of inflammation.

Salicylic acid is known to be effective in the treatment of acne. It is a topical
keratolytic agent that works by dissolving the intercellular cement that holds
epithelial cells together. Salicylic acid is used in a variety of over-the-counter
20 acne remedies.

In order to improve the efficacy of topical acne treatments, it is desired to
formulate salicylic acid with one or more oil control agents such as sebum
regulators which regulate the number of active glands or oil absorbing agents
25 which remove excess oil from the skin. In order to ensure optimum
performance, it is necessary to suspend the oil control agents in the skincare
composition. However, a problem arises when producing such formulations
as the ingredients necessary to suspend the oil control agents are less stable
at the acidic pH of the salicylic acid compositions and satisfactory
30 suspensions may not be formed. For example, using carbomer (trade name

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- Carbopol, available from B.F. Goodrich) as the thickener in an aqueous carrier, it was found that combining salicylic acid with oil control agents such as talc, charcoal, rice starch and clay led to compositions which did not maintain the oil control agent in suspension for a satisfactory period. Similar
- 5 results were also obtained with thickeners such as Acrylates/Palmeth-25 Acrylate copolymer (available from 3V Sigma S.P.A under the trade name Synthalen W2000) and xanthan gum (available from Kelco under the trade name Keltrol RD). In addition, it was found that incorporating sebum regulators such as Algae Extract, Burdock Extract, Watercress Extract and
- 10 10 Orange extract into salicylic acid compositions led to compositions which were unable to form an acceptable hydro-lipid film on the skin, this being desired to restore the equilibrium of all skin types by regulation of the number of active glands.
- 15 Surprisingly, it has now been found that skincare compositions comprising salicylic acid and hydrolysed milk protein have improved therapeutic efficacy in the treatment of acne. Said skincare compositions have both the ability to treat acne and establish a normal hydro-lipid film on the skin.
- 20 Hydrolysed milk protein is the hydrolysate of milk protein derived by acid, enzyme or other method of hydrolysis. Hydrolysed milk protein has previously been known for use to condition hair and skin. It may be used as a sebum regulator to restore the flow of sebum in dry skin and reduce excessive production of sebum in oily skin. It has not previously been
- 25 employed as an active agent in the treatment of acne. However, in view of the results obtained with other oil control agents, it is surprising that hydrolysed milk protein in combination with salicylic acid has such a marked effect. For example, it has been shown that stable suspensions can be formed even at acid pH. In addition, trials show a delay in the re-greasing of
- 30 the skin and the achievement of significant sebum reduction even after a few

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days, for example three days, even with compositions that are rinsed off after application. With this combination, effective treatment of acne can be achieved as it is possible to restore the equilibrium of all skin types by normalising the sebum flow through controlling the production of the sebum 5 and regulating the number of effective glands, even taking into account the over-drying and irritating effects of salicylic acid on the skin. Furthermore, the salicylic acid compositions are found to be well tolerated by the skin. This is particularly important as salicylic acid compositions can cause some degree of local skin peeling and discomfort such as burning and skin 10 reddening.

Thus, according to a first aspect of the invention there is provided a skincare composition suitable for topical application to the skin, said composition comprising salicylic acid or a salt thereof and hydrolysed milk protein. 15 Salicylic acid is preferably incorporated into the composition according to the invention as the free acid. However, the pH of the composition may, and generally will, be such that the salicylic acid exists in the composition in dissociated form. As the composition may well contain cationic counterions, 20 the salicylic acid may then be thought of as being present in salt form. Alternatively, the salicylic acid may be incorporated into the composition in salt form, eg as a salt with a Group I metal, such as sodium salicylate. As used herein, unless the context requires otherwise, any and all references to 25 salicylic acid should be taken to encompass references to the acid and to dissociated forms and salts thereof.

The concentration of salicylic acid in the composition according to the invention is preferably at least 0.01% by weight, more preferably at least 0.1%, most preferably at least 0.5% and especially at least 1% by weight. 30 The concentration of salicylic acid is preferably less than 10%, more

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preferably less than 5%, most preferably less than 4% and especially less than 3% by weight. The concentration of salicylic acid may therefore fall in the range 0.01% to 10% by weight, more preferably 0.1% to 5%, and most preferably 0.5% to 4% and especially 1 to 3% by weight. A particularly preferred concentration of salicylic acid is 2% by weight.

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The concentration of hydrolysed milk protein in the composition according to the invention is preferably at least 0.01% by weight, more preferably at least 0.05% by weight, most preferably at least 0.08% by weight and especially at 10 least 0.1% by weight. The concentration of hydrolysed milk protein is preferably less than 10%, more preferably less than 3%, most preferably less than 2% and especially less than 1% by weight. The concentration of hydrolysed milk protein may therefore fall within the range 0.01% to 10% by weight, more preferably 0.05% to 3%, most preferably 0.08% to 2% and 15 especially 0.1 to 1.0% by weight. A particularly preferred concentration of hydrolysed milk protein is 0.2% by weight.

10

The composition is preferably prepared with a pH in the range 2.3 to 7.0, more preferably 2.5 to 6.0, and particularly a pH in the range 2.5 to 4.0, eg 20 about pH 3.0 or pH 3.5.

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The composition according to the invention may comprise one or more topically active ingredients useful in skincare. Such active ingredients may include one or more of the following:

antimicrobial or antibacterial compounds, for example selected from the following:

triclosan, neomycin, clindamycin, polymyxin, bacitracin, benzoyl peroxide, hydrogen peroxide, tetracyclines such as doxycycline or minocycline, sulfa

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drugs such as sulfacetamide, penicillins, cephalosporins such as cephalexin, and quinolones such as lomefloxacin, ofloxacin or trovafloxacin;

5 antiviral compounds, for example selected from acyclovir, tamvir, and penciclovir;

antifungal compounds, for example selected from the following: farnesol, clotrimazole, ketoconazole, econazole, fluconazole, calcium or zinc undecylenate, undecylenic acid, butenafine hydrochloride, ciclopirox 10 olamine, miconazole nitrate, nystatin, sulconazole, and terbinafine hydrochloride;

anti-inflammatory compounds, for example selected from the following: steroid agents selected from hydrocortisone, fluocinolone acetonide, 15 halcinonide,

halobetasol propionate, clobetasol propionate, betamethasone dipropionate, betamethasone valerate, and triamcinolone acetonide, and non-steroidal anti-inflammatory agents selected from aspirin, ibuprofen, ketoprofen, naproxen, aloe vera gel, aloe vera, licorice extract, pilewort, Canadian willow 20 root, zinc, and allantoin;

anthelmintic compounds, for example metronidazole.

Particularly suitable antibacterial agents are peroxide antibacterial agents. A 25 preferred peroxide antibacterial agent for inclusion in the composition is hydrogen peroxide. Alternatively, the composition may comprise a compound that, in use, is capable of generating hydrogen peroxide. An example of the latter class of compound is an adduct such as urea peroxide (carbamide peroxide).

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In one preferred embodiment of the invention, the composition comprises both salicylic acid and hydrogen peroxide.

- Where hydrogen peroxide is present in the composition according to the invention, the concentration of hydrogen peroxide is preferably at least 1% by weight. The concentration of hydrogen peroxide is preferably less than 5%, more preferably less than 3%, and most preferably less than 2%. The concentration of hydrogen peroxide may therefore fall within the range 1% to 5% by weight, more preferably 1% to 3%, and most preferably 1% to 2%.
- 10

The composition according to the invention may also comprise one or more ingredients which have a cooling effect on the skin, for example volatile ingredients, such as menthol.

- 15 The composition according to the invention may be applied and left on the skin to have the desired therapeutic effect or it may be applied and then rinsed off, for example with water. The composition may be applied with the aid of a fibrous material, for example a pad or a wipe.
- 20 The composition according to the invention may be formulated in numerous forms. However, the composition may often take the form of an aqueous or oily solution or dispersion or emulsion or a gel. An emulsion may be an oil-in-water emulsion or a water-in-oil emulsion.
- 25 The oil phase of water-in-oil or oil-in-water emulsions may comprise for example:
- hydrocarbon oils such as paraffin or mineral oils;
 - waxes such as beeswax or paraffin wax;

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- c) natural oils such as sunflower oil, apricot kernel oil, shea butter or jojoba oil;
- d) silicone oils such as dimethicone, cyclomethicone or cetyltrimethicone;
- e) fatty acid esters such as isopropyl palmitate, isopropyl myristate, dioctylmaleate, glyceryl oleate and cetostearyl isononanoate;
- 5 f) fatty alcohols such as cetyl alcohol or stearyl alcohol and mixtures thereof (eg cetostearyl alcohol);
- g) polypropylene glycol or polyethylene glycol ethers, eg PPG-14 butyl ether; or
- 10 h) mixtures thereof, for example, the blend of waxes available commercially under the trade name Cutina (Henkel).

Emulsifiers used may be any emulsifiers known in the art for use in water-in-oil or oil-in-water emulsions. Known cosmetically acceptable emulsifiers include:

- 15 a) sesquioleates such as sorbitan sesquioleate, available commercially for example under the trade name Arlacel 83 (ICI), or polyglyceryl-2-sesquioleate;
- b) ethoxylated esters of derivatives of natural oils such as the 20 polyethoxylated ester of hydrogenated castor oil available commercially for example under the trade name Arlacel 989 (ICI);
- c) silicone emulsifiers such as silicone polyols available commercially for example under the trade name ABIL WS08 (Th. Goldschmidt AG);
- d) anionic emulsifiers such as fatty acid soaps e.g. potassium stearate and 25 fatty acid sulphates e.g. sodium cetostearyl sulphate available commercially under the trade name Dehydag (Henkel);
- e) ethoxylated fatty alcohols, for example the emulsifiers available 30 commercially under the trade name Brij (ICI);
- f) sorbitan esters, for example the emulsifiers available commercially under the trade name Span (ICI);

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- g) ethoxylated sorbitan esters, for example the emulsifiers available commercially under the trade name Tween (ICI);
- h) ethoxylated fatty acid esters such as ethoxylated stearates, for example the emulsifiers available commercially under the trade name Myrij (ICI);
- 5 i) ethoxylated mono-, di-, and tri-glycerides, for example the emulsifiers available commercially under the trade name Labrafil (Alfa Chem.);
- j) non-ionic self-emulsifying waxes, for example the wax available commercially under the trade name Polawax (Croda);
- k) ethoxylated fatty acids, for example, the emulsifiers available
- 10 commercially under the trade name Tefose (Alfa Chem.);
- l) methylglucose esters such as polyglycerol-3 methyl glucose distearate available commercially under the name Tegocare 450 (Degussa Goldschmidt); or
- m) mixtures thereof.

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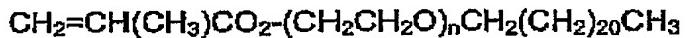
- The gels according to the invention may be aqueous or non-aqueous. Aqueous gels are preferred. The gel will contain a thickening agent or gelling agents in order to give sufficient viscosity to the gel. A variety of thickening agents may be used according to the nature of the liquid carrier and the viscosity required.
- 20 Thickeners that are water-soluble or hydrophilic are preferred, and examples include acrylic acid polymers, eg those available commercially under the trade name Carbopol (B.F. Goodrich), modified celluloses, eg hydroxypropylmethylcellulose or hydroxyethylcellulose available commercially under the trade name Natrosol (Hercules), alkylgalactomanans available under
- 25 the trade name N-Hance, xanthan gum, cetyl alcohol and sodium chloride. A particularly suitable thickener is a copolymer of acryloyl dimethyl tauric acid (or a salt thereof) is a copolymer of that monomer with another vinylic monomer. For example, the thickening agent is a copolymer of a salt of acryloyl dimethyl tauric acid with another vinylic monomer. The salt may be

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a salt of a Group I alkali metal, but is more preferably an ammonium salt. Examples of suitable copolymer thickening agents are:

- i) Ammonium acryloyl dimethyl taurate / vinyl pyrrolidone copolymer, ie a 5 copolymer of ammonium acryloyl dimethyl taurate and vinyl pyrrolidone (1-vinyl-2-pyrrolidone). This material is available under the trade name Aristoflex AVC from Clariant GmbH, Functional Chemicals Division, D-65840 Sulzbach, Germany.
- 10 ii) Ammonium acryloyl dimethyl taurate / Beheneth-25 methacrylate copolymer, ie a copolymer of ammonium acryloyl dimethyl taurate and Beheneth-25 methacrylate, the structure of which is



- 15 in which n is approximately 25. This material is also available from Clariant GmbH under the trade name Aristoflex HMB.

- 20 iii) Ammonium acryloyldimethyltaurate / vinyl formamide copolymer, ie a copolymer of ammonium acryloyl dimethyl taurate and vinyl formamide. Again, a suitable material is available from Clariant GmbH under the trade name Aristoflex AVC-1.

- 25 The composition most preferably comprises less than 10% w/w of the thickening agent, and more commonly less than 5% w/w. The amount of thickening agent will generally be greater than 0.1% w/w and more commonly greater than 0.5% w/w. The amount of thickening agent in the composition will preferably lie in the range 0.1 to 5% w/w, more preferably 0.5 to 5% w/w. Typically, the amount of thickening agent will be less than 30 3% w/w, eg about 1% w/w or about 2% w/w.

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The composition according to the invention preferably has a viscosity of from about 50 mPa.s to about 20,000 mPa.s, more preferably from about 100 mPa.s to about 10,000 mPa.s. Viscosity may be measured using a

- 5 Brookfield RVT viscometer equipped with a spindle 4 rotating at 10rpm after 2 minutes.

In many instances, it is preferred that the composition should comprise a chelating or sequestering agent, or other agent capable of complexation or

- 10 other interaction with metal ions present in the composition. Such agents may improve the stability of the composition, and in particular may inhibit or prevent degradation of several ingredients (eg fragrance). Examples of chelating or sequestering agents include ethylenediamine tetraacetic acid and its salts, notably the dipotassium and especially the disodium salt.

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- In the case of solutions or dispersions, and gels, the composition will generally contain a solvent system or other continuous liquid phase. Such a system is preferably aqueous. However, mixed solvent systems may often be used with advantage. Such a mixed solvent system most preferably comprises water, in
20 admixture with a co-solvent, most preferably a lower (eg C₁₋₆) alcohol, in particular ethanol and t-butyl alcohol.

- Preferred aqueous systems comprise water in an amount of at least 50% by weight, more preferably at least 60% by weight, most preferably at least 70%
25 by weight and especially at least 80% by weight. The upper limit of water will depend on the amounts of other ingredients incorporated in the composition so that the water may form the remainder of the composition up to 100% of the composition. A typical maximum value is less than 90% by weight, for example 80% by weight or 85% by weight.

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- The composition most preferably comprises in excess of 5% w/w of the cosolvent, and may comprise in excess of 10% w/w, in excess of 20% w/w, or in excess of 30% w/w of the cosolvent. The amount of cosolvent present in the composition preferably does not exceed 50% w/w. The amount of
- 5 cosolvent thus preferably lies in the range 5% to 50% w/w, more preferably 10% to 50% w/w. In general, higher proportions of cosolvent may be required in compositions containing higher proportions of ingredients (eg topically active ingredients, as discussed below) that are of low solubility in water. Where such ingredients are absent, of their concentration is relatively
- 10 low, the proportion of cosolvent may also be somewhat lower than in other embodiments, eg up to 20% w/w.

The composition may additionally comprise other components which will be well known to those skilled in the art. These include, for example:

- 15 a) Emollients – ingredients that help to maintain the soft, smooth and pliable appearance of skin. Such ingredients may function by their ability to remain on the surface of the skin or in the stratum corneum, and to act as lubricants, reducing or preventing flaking of the skin and improving the skin's appearance.
- 20 Examples of emollients are isopropyl myristate, triglycerides of fatty acids eg lauric triglyceride or capric/caprylic triglyceride, such as the triglyceride available commercially under the trade name Miglyol 810 (Huls UK), and the polypropylene glycol ether of stearyl alcohol known as PPF-15 Stearyl Ether. Particularly preferred emollients are polysiloxane compounds, in particular
- 25 those known as cyclomethicone, ie cyclic dimethyl polysiloxane compounds that conform to the formula:



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in which n has a value between 3 and 7.

- b) Humectants or Moisturisers – ingredients intended to increase the water content of the top layers of the skin. Examples of such ingredients are glycerin,
- 5 1,3-butylene glycol and propylene glycol.
- c) Surfactants – Surfactants may be used in compositions according to the invention as solubilisers, or as cleansing agents or foam boosters. Many different classes of surfactant may be suitable for inclusion in the
- 10 composition according to the invention, and these will be readily apparent to those skilled in the art. Examples of suitable surfactants include polyethylene glycol ethers of alcohols such as isocetyl alcohol (eg Isoceteth-20), isostearyl alcohol (eg Isosteareth-20), cetyl alcohol (eg Ceteth-20), oleyl alcohol (eg Oleth-20) and cetearyl alcohol (eg Ceteareth-20). A particularly preferred surfactant for use in the invention is Isoceteth-20.
- d) Emulsion stabilising salts such as sodium chloride, sodium citrate or magnesium sulphate.
- 20 e) Preservatives – ingredients which prevent or retard microbial growth and thus protect the composition from spoilage. Examples of preservatives include such as propylparaben, bronopol, sodium dehydroacetate, polyhexamethylenebiguanide hydrochloride, isothiazolone and diazolidinylurea.
- f) Chelating agents or sequestering agents (sequestrants) – ingredients that have the ability to complex with and inactivate metallic ions in order to prevent their adverse effects on the stability or appearance of the composition, as described above. Examples of chelating agents are ethylenediamine tetraacetic acid and its salts, notably the dipotassium and especially the
- 30 disodium or tetrasodium salt.

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- g) Abrasives – ingredients used to assist in the removal of unwanted tissue or foreign materials from the skin during application of the composition. Abrasives commonly comprise fine solid particles. One example of a suitable abrasive is
- 5 polyethylene beads.
- h) pH adjusters – Ingredients used to control the pH of the composition. Examples of pH adjusters are inorganic salts such as sodium hydroxide, and organic bases such as triethanolamine.
- 10 i) Surfactants – In addition to their use as emulsifying agents, surfactants may be used in compositions according to the invention as cleansing agents, foam boosters or solubilising agents. Many of the emulsifying agents referred to above may be used for these purposes, and other suitable surfactants will be
- 15 readily apparent to those skilled in the art.
- j) Conditioning agents, for example distearyldimonium chloride.
- k) Perfumes and colourings.
- 20 According to another aspect of the invention, there is provided a fibrous material, for example in the form of a pad or a wipe, impregnated with a skincare composition comprising salicylic acid or a salt thereof and hydrolysed milk protein. The fibrous material may be used to apply the
- 25 composition onto the skin.
- Preferably, said fibrous material is impregnated with the skincare composition in an amount in the range from 10 to 30% by weight, preferably from 15 to 25% by weight and most preferably from 18 to 22% by weight of the fibrous material.
- 30 Suitable fibrous materials include cellulose or cotton fibres or a mixture thereof.

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- The fibrous material may be impregnated with the composition as a wet wipe which is arranged for immediate use to apply the skincare composition of the present invention to the skin of the user. Alternatively, the fibrous material may be impregnated with the skincare composition and dried to form a dry wipe
- 5 which requires to be wetted, for example with water, before it can be used.

- According to a further aspect of the invention, there is provided method for the prophylactic or remedial treatment of acne, which method comprises the topical application to the skin of a patient of a skincare composition
- 10 comprising salicylic acid or a salt thereof and hydrolysed milk protein.

- It will be appreciated that the method according to this aspect of the invention may be a therapeutic method, but will often be a primarily cosmetic method, the objective of which is to reduce or eliminate externally visible,
- 15 and often unsightly, symptoms of acne vulgaris.

- In a yet further aspect of the invention, there is provided the use of salicylic acid and hydrolysed milk protein in the manufacture of a composition for the prophylactic or remedial treatment of acne by topical application of the
- 20 composition to the skin.

The invention will now be described in greater detail, by way of illustration only, with reference to the following Examples.

25 Example 1

Oil Control Cream Wash

Ingredients	%w/w
Sodium cocyl isethionate	16.40
30 Cetyl alcohol	10.00

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	Laureth-3	5.00
	Glycerin	3.00
	Salicylic acid	2.00
	Sodium hydroxide	0.36
5	Hydrolysed Milk Protein	0.20
	Parfum	0.20
	Disodium EDTA	0.01
	Aqua	to 100%

10 Method

Heat the cetyl alcohol and laureth-3 to 60°C to form the oil phase. Premix the remainder of the ingredients to form the aqueous phase. Add the oil phase to the aqueous phase. Cool the composition down to room temperature with stirring to form a uniform composition.

15

Example 2Scrub Wipe

	<u>Ingredients</u>	%w/w
20	PPG-14 butyl ether	8.00
	Cetearyl isononoate	2.25
	Salicylic acid	2.00
	Ceteareth-20	1.13
25	Cetearyl alcohol	1.13
	Glyceryl Stearate	0.45
	Glycerin	0.45
	Hydrolysed Milk Protein	0.20
	Hydrogen peroxide	1.50
30	Menthol	0.10
	Disodium EDTA	0.10

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Cetyl palmitate	0.15
Ceteareth palmitate	0.15
Parfum	0.10
Aqua	to 100%

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Method

Mix and heat all ingredients, apart from hydrolysed milk protein, menthol and parfum, to 90°C. Cool the mixture down to room temperature with stirring.
Stir the remaining ingredients into the mixture to form a uniform composition.

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Example 3Gel Wash

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	<u>Ingredients</u>	<u>%w/w</u>
	Laureth sulphate	11.9
	Coco glucoside	4.0
	Glycerin	3.0
20	Salicylic acid	2.0
	Sodium chloride	1.6
	Hydrolysed Milk Protein	0.2
	Parfum	0.2
	Menthol	0.1
25	Aqua	to 100%

Method

Mix all the ingredients at room temperature to form a uniform composition.

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Example 4Lotion for Impregnated Pads

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	<u>Ingredients</u>	<u>%w/w</u>
	Alcohol(99.9%)	
	and t-Butylalcohol(0.1%)	37.00
5	Isoceteth-20	3.00
	Salicylic acid	2.00
	Hydrogen Peroxide (active 35%)	4.29
	Hydrolysed Milk Protein (mixed with propylene glycol and water)	0.20
10	Sodium hydroxide (30%)	0.20
	Parfum	0.10
	Disodium EDTA	0.005
	Aqua	to 100%

15 Method

Mix all the ingredients at room temperature to form a uniform composition.

Example 5**20 Cream Scrub**

	<u>Ingredients</u>	<u>%w/w</u>
	Stearyl alcohol	3.00
	Cetyl alcohol	1.00
25	Salicylic acid	2.00
	Glycerin	3.00
	Xanthan gum	0.20
	Steareth-21	0.50
	Steareth-2	0.25
30	Distearyldimoniumchloride	1.50

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	Behenyl alcohol	0.42
	PPG-15 Stearyl ether (99.9%) and BHT (0.1%)	4.00
5	Mixture of Cetyl betaine (30%), sodium chloride (7%), alcohol (10%), water (10%)	6.70
	Sodium lauryl sulphate	3.60
	Polyethylene beads	4.00
	Hydrolysed Milk Protein	
10	(mixed with propylene glycol and water)	0.20
	Synthetic wax and mica beads	0.35
	Parfum	0.20
	Disodium EDTA	0.01
	Aqua	to 100%

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Method

- Heat the stearyl alcohol, cetyl alcohol, behenyl alcohol, steareth-21, steareth-2, distearyldimoniumchloride, PPG-15 stearyl ether and BHT to 60°C to form the oil phase. Premix the remainder of the ingredients to form the aqueous phase. Add the oil phase to the aqueous phase. Cool the composition down to room temperature with stirring.

Example 625 Gel Lotion

	<u>Ingredients</u>	<u>% w/w</u>
	Alcohol (99.9%) + t-butylalcohol (0.1%)	11.5
30	Glycerin	0.50

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	Isoceteth-20	1.00
	Salicylic acid	0.50
	Hydrogen peroxide (35%)	4.29
	Ammonium acryloyldimethyltaurate/	
5	vinyl pyrrolidone copolymer	1.50
	Hydrolyzed Milk Protein	0.20
	Sodium hydroxide (30%)	0.40
	Parfum	0.20
	Disodium EDTA	0.005
10	Aqua	to 100%

Method

Mix the salicylic acid into the alcohol/t-butylalcohol. When the salicylic acid is fully dissolved, mix in the water, glycerin and disodium EDTA. Add the 15 ammonium acryloyldimethyltaurate / vinyl pyrrolidone copolymer with continuous homogenisation. Then add the isoceteth-20, hydrogen peroxide, hydrolysed milk peptide, parfum in the water. Adjust the pH to 3 with sodium hydroxide (30%).

20 Example 7Lotion

	<u>Ingredients</u>	<u>% w/w</u>
25	Sorbitol (70%)	0.50
	Denatured ethanol	37.00
	Glycerin	1.50
	Isoceteth-20	2.00
	Salicylic acid	2.00
30	Hydrolyzed Milk Protein	0.20

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Sodium hydroxide (30%)	0.38
Parfum	0.10
Aqua	to 100%

5 Method

Dissolve the salicylic acid, isoceteth-20 and parfum in the ethanol to form the oil phase. Mix the remaining ingredients with the water to form the aqueous phase. Mix the oil and aqueous phase to form a uniform composition.

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Example 8Lotion for Impregnated Pads

	<u>Ingredients</u>	<u>% w/w</u>
	Sorbitol (70%)	0.50
	Denatured ethanol	37.00
	Hydrogen Peroxide	4.29
20	Isoceteth-20	3.00
	Salicylic acid	2.00
	Hydrolyzed Milk Protein	0.20
	Sodium hydroxide (30%)	0.20
	Parfum	0.10
25	Disodium EDTA	0.005
	Aqua	to 100%

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Method

Dissolve the salicylic acid, isoceteth-20 and parfum in the ethanol to form the oil phase. Mix the remaining ingredients with the water to form the aqueous phase. Mix the oil and aqueous phase to form a uniform composition.

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Claims

1. A skincare composition suitable for topical application to the skin, the composition comprising salicylic acid or a salt thereof and hydrolysed milk protein.
2. A composition as claimed in Claim 1, which comprises salicylic acid.
3. A composition as claimed in Claim 2, wherein the concentration of salicylic acid is at least 0.01% by weight, more preferably at least 0.1% by weight and most preferably at least 1% by weight.
4. A composition as claimed in Claim 2, wherein the concentration of salicylic acid is less than 10% by weight, more preferably less than 5% by weight, and most preferably less than 3% by weight.
5. A composition as claimed in Claim 2, wherein the concentration of salicylic acid is in the range from 0.01% to 10% by weight, more preferably from 0.1% to 5% by weight, and most preferably from 1% to 3% by weight.
6. A composition as claimed in Claim 1, wherein the concentration of hydrolysed milk protein is at least 0.01% by weight, more preferably at least 0.05% by weight, and most preferably at least 0.1% by weight.
7. A composition as claimed in Claim 1, wherein the concentration of hydrolysed milk protein is less than 10% by weight, more preferably less than 3% by weight, and most preferably less than 1% by weight.
8. A composition as claimed in Claim 1, wherein the concentration of hydrolysed milk protein is in the range from 0.01% to 10% by weight, more

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preferably from 0.05% to 3% by weight, and most preferably from 0.1% to 1.0% by weight.

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- 5 9. A composition as claimed in claim 1, wherein the concentration of salicylic acid is in the range from 0.5 to 4% by weight, more preferably from 0.5 to 2% by weight and the concentration of hydrolysed milk protein is in the range from 0.08 to 2%, more preferably from 0.1 to 0.5 % by weight.
- 10 10. A composition as claimed in any preceding claim, wherein the ratio of salicylic acid or salt thereof to hydrolysed milk protein is in the range from 1:1 to 20:1 parts by weight, more preferably from 2:1 to 15:1 parts by weight, most preferably from 5:1 to 12:1 parts by weight.
- 15 11. A composition as claimed in any preceding claim, wherein the pH of the composition is in the range from 2.3 to 7.0, more preferably from 2.5 to 6.0.
- 20 12. A composition as claimed in Claim 11, wherein the pH is in the range from 2.5 to 4.0.
13. A composition as claimed in any preceding claim, which further comprises a thickening agent.
- 25 14. A composition as claimed in Claim 12, wherein the thickening agent is a copolymer of acryloyl dimethyl tauric acid or a salt thereof.
15. A composition as claimed in any preceding claim further comprising one or more topically active skincare agents selected from an anti-microbial

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or anti-bacterial compound, an anti-viral compound, an anti-fungal compound, an anti-inflammatory compound and an anthelmintic compound.

16. A composition as claimed in claim 15 wherein the anti-bacterial agent
5 is a peroxide anti-bacterial agent.

17. A composition as claimed in any preceding claim, which has the form of an aqueous or oily solution or dispersion or emulsion or a gel.

10 18. A composition as claimed in any preceding claim, which is in the form of an emulsion.

19. A composition as claimed in Claim 18, wherein the emulsion is an oil-in-water emulsion.

15 20. A composition as claimed in Claim 18, wherein the emulsion is a water-in-oil emulsion.

21. A composition as claimed in claim 17, which is in the form of an
20 aqueous gel.

22. A composition as claimed in any preceding claim, which comprises an aqueous solvent system.

25 23. A composition as claimed in Claim 22, wherein the solvent system is a mixed solvent system comprising water in admixture with a co-solvent.

24. A composition as claimed in Claim 23, wherein the co-solvent is an alcohol.

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25. A composition as claimed in any preceding claim, which comprises one or more excipients selected from the group consisting of emulsifiers, emollients, lipids, humectants or moisturisers, binders, conditioning agents, emulsion stabilising salts, preservatives, chelating agents or sequestering agents, abrasives, pH adjusters, surfactants, perfumes and colourings.
- 5
26. A fibrous material impregnated with a skincare composition as claimed in any preceding claim.
- 10 27. A fibrous material as claimed in claim 26, wherein the fibrous material is impregnated with the skincare composition in an amount in the range from 10 to 30% by weight, preferably from 15 to 25% by weight and most preferably from 18 to 22% by weight of the fibrous material.
- 15 28. A fibrous material as claimed in either one of claims 26 or 27 comprising cellulose or cotton fibres or a mixture thereof.
- 20 29. A method for the prophylactic or remedial treatment of acne, which method comprises the topical application to the skin of a patient of a skincare composition as claimed in any one of claims 1 to 25.
30. A method as claimed in Claim 29, which is a cosmetic method.
31. A method as claimed in Claim 29, which is a therapeutic method.
- 25
32. The use of salicylic acid or a salt thereof and hydrolysed milk protein in the manufacture of a composition for the prophylactic or remedial treatment of acne by topical application of the composition to the skin.

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33. The use as claimed in claim 32 wherein salicylic acid or a salt thereof and hydrolysed milk protein are the sole active ingredients in the composition.

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